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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,126	06/22/2001	Jennifer L. Schmitke	2685.2030-000	9053

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/888,126
Filing Date: June 22, 2001
Appellant(s): SCHMITKE ET AL.

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/28/2005 appealing from the Office action mailed January 11, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

A related Appeal in U.S. Patent Application No. 10/179,463.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,997,848	Patton et al	12-1999
5,985,309	Edwards et al	11-1999

(9) Response to Arguments

From the Applicant's rebuttal arguments, it is safe to conclude that Applicant agrees that the examiner has established a *prima facie* case of obviousness. However applicant argues that there is evidence establishing significant unexpected results, mostly due to specific amounts of the components. Applicant refers to the Declarations submitted which shows a comparative data of formulations with various concentrations. The table shows various "crash out" times.

It is noted that the declaration is showing a study carried out on solubility of solids in solutions. The conclusion made is that "the solubility of the insulin formulation is not dictated solely by DPPC solubility". On the other hand the statement just below figure 2 reads "Figure 2 shows that higher insulin content appears to stay in solution longer (i.e., have higher "crash-out" times). This could be because higher insulin content translates to a lower DPPC content ". Thus it can be concluded that there is no showing of an unexpected results where unexpectedly applicant discovered a formulations containing 30% insulin and 60% DPPC was stable and effective. The statement is

mostly showing that the "higher insulin content" the more stable the formulation. A rather exponential relationship between amounts of insulin and stability. It is then concluded that the Applicant has not met their burden of showing the criticality of the 30% insulin and/or 60% DPPC formulations.

Furthermore, as stated in the Final Office Action, it is believed that Applicant has not shown a side-by-side comparison of their formulations with the formulations of prior art. Contrary to Applicant's arguments, Patton discloses specific amounts of insulin in formulations in an example. In column 11, Patton discloses three formulations that were tested in rats, which contain 87.9% insulin or 20% insulin. Formulation No. 3 contains 20% insulin, 12.4% sodium citrate and 66% raffinose. By substituting DPPC for raffinose (Edwards also teaches adding about 60% of DPPC to the formulations), one would end up with a formulation very close in concentration ranges as that claimed by the Applicant (30/10/60). Applicant failed to show a direct comparison of these the claimed formulations with the prior art formulations. Patton is also concerned with stability of the formulations and states that carriers and buffers are chosen to enhance stability of the formulation (see for example, col. 3, line 66 to col. 4, line 4 and col. 6, first paragraph). Thus it is concluded that Patton has disclosed a formulation with very close concentration ranges of contents to those of the instant claims.

Applicant also believes that, if claim 1 is not allowable, claim 18 is separately allowable because it recites a formulation administered to the patient in a single breath-actuated step. Applicant argues that such method is not disclosed by Patton or Edwards. The argument is not persuasive because the method of administration via a

single breath-actuated step is obvious to one of ordinary skill in the art. Prior art has clearly established such methods as known and practiced in the field of inhalations. In other words, the method is known in the art for the same purpose.

Applicant argues that if claim 1 is not allowable, then claim 39 is separately allowable because it recites rapid release of insulin upon simultaneous inhalation. This is not persuasive because this rate of release of the drug is a property of the formulation. When it is established that the formulation is obvious over the combined references, its rate of release would be the same.

Applicant argues that, if claim 1 is not allowable, then claims 59 and 60 are separately allowable because neither Patton nor Edwards teach low transition temperature phospholipids. This is not true. Edwards teaches that suitable surfactants include natural or synthetic surfactants such as DPPG and DPPC can be used in the formulation. According to the art and Applicant's own disclosure, both DPPG and DPPC are low transition temperature phospholipids (pages 11-12).

A Terminal Disclaimer was filed with the Reply to Final Office Action and has been entered. The Double Patenting rejection of claims over Application serial No. 10/179,463 is withdrawn.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Mina Haghighatian

September 12, 2005

Conferees:

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